

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
 US Department of Commerce  
 United States Patent and Trademark  
 Office, PCT  
 2011 South Clark Place Room  
 CP2/5C24  
 Arlington, VA 22202  
 ETATS-UNIS D'AMERIQUE  
 in its capacity as elected Office

<b>Date of mailing</b> (day/month/year) 01 December 2000 (01.12.00)	<b>Applicant's or agent's file reference</b> PF-0661 PCT
<b>International application No.</b> PCT/US00/01565	<b>Priority date</b> (day/month/year) 22 January 1999 (22.01.99)
<b>International filing date</b> (day/month/year) 21 January 2000 (21.01.00)	
<b>Applicant</b> HILLMAN, Jennifer, L. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

27 July 2000 (27.07.00)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
 34, chemin des Colombettes  
 1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Pascal Piriou

Telephone No.: (41-22) 338.83.38

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

## PCT

### NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

To: DIANA HAMLET-COX  
INCYTE PHARMACEUTICALS, INC.  
3171 PORTER DRIVE  
PALO ALTO, CA 94304

Date of Mailing  
(day/month/year)

**15 AUG 2002**

Applicant's or agent's file reference

PF-0661 PCT

#### IMPORTANT NOTIFICATION

International application No.

PCT/US00/01565

International filing date (day/month/year)

21 JANUARY 2000

Priority Date (day/month/year)

22 JANUARY 1999

Applicant

INCYTE PHARMACEUTICALS, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB 301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US  
Commissioner of Patents and Trademarks  
Box 187  
Washington, D.C. 20231

Facsimile No. 703 305-3230

Authorized officer

Alana M. Harris, PH.D.

Telephone No. 703 305-6196

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PF-0661 PCT	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/01565	International filing date (day/month/year) 21 JANUARY 2000	Priority date (day/month/year) 22 JANUARY 1999
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant INCYTE PHARMACEUTICALS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and or drawings which have been amended and are the basis for this report and or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 0 sheets.

## 3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 27 JULY 2000	Date of completion of this report 25 JULY 2002
Name and mailing address of the IPEA US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer Alana M. Harris, PH.D. <i>Alana M. Harris</i>
Facsimile No. 703 305-3230	Telephone No. 703 308-0196

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/01565

## 1. Basis of the report

1. With regard to the elements of the international application:\*

☒ the international application as originally filed

☒ the description:

pages 1-56 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_

☒ the claims:

pages 57-59 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_

☒ the drawings:

pages 1-19 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_

☒ the sequence listing part of the description:

pages 1-9 \_\_\_\_\_, as originally filed  
pages NONE \_\_\_\_\_, filed with the demand  
pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE  
☒ the claims, Nos. NONE  
☒ the drawings, sheets fig. NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/01565

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	<u>7, 12 and 16-23</u>	YES
	Claims	<u>1-6, 8-11, 13-15</u>	NO
Inventive Step (IS)	Claims	<u>none</u>	YES
	Claims	<u>1-23</u>	NO
Industrial Applicability (IA)	Claims	<u>1-23</u>	YES
	Claims	<u>none</u>	NO

**2. citations and explanations (Rule 70.7)**

Claims 1-6, 8-11 and 13-15 lack novelty under PCT Article 33(2) as being anticipated by Chen et al. (The Journal of Biological Chemistry 273(28):17618-17625, July 16, 1998). These references disclose an isolated polypeptide comprising a naturally occurring amino acid sequence having at least 90% sequence identity to SEQ ID NO:2, as well as biologically active and immunogenic fragments of SEQ ID NO:2. Figure 3 of the Chen reference discloses the encoded polypeptide. The paper also discloses an isolated antibody that is capable of binding to the polypeptide.

Claims 7, 12 and 16-23 lack an inventive step under PCT Article 33(3) as being obvious over Chen et al. (The Journal of Biological Chemistry 273(28):17618-17625, July 16, 1998). These references are discussed above. The Chen reference suggests that the disclosed polypeptide has potential use in an immunotherapy method for treating prostate and other cancers. With the treatment of patients one of skill in the art could easily screen the compounds for their effectiveness.

## ----- NEW CITATIONS -----

CHEN et al. Isolation and characterization of PAGE-4 and GAGE-7. The Journal of Biological Chemistry. 10 July 1998, Vol. 273, pages 17618-17625.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/01565

## Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Sheet 10

Continuation of: Boxes I - VIII

### CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): A61K 35/14, 38/00, 38/16; C 07K 1/00, 14/00, 16/00, 17/00; C07H 5/04, 5/06, 19/00, 21/00, 21/02, 21/04, C08B 37/00, C12P 21/06 4/00, 21/08, C12Q 1/68; C12N 5/00, G01N 33/00, 7/00, 14/00, 17/00 and US Cl.: 435/4, 6, 69.1, 325, 530/300, 350, 380, 385, 386, 387.1, 387.1; 536/1, 18.7, 22.1, 23.1, 23.5, 23.53

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>PF-0661 PCT</b>	<b>FOR FURTHER ACTION</b>		see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below
International application No. <b>PCT/US 00/01565</b>	International filing date (day/month/year) <b>21/01/2000</b>	(Earliest) Priority Date (day/month/year) <b>22/01/1999</b>	
Applicant <b>INCYTE PHARMACEUTICALS, INC. et al.</b>			

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:
- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

**4. With regard to the title,**



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

**5. With regard to the abstract,**



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.



None of the figures.



as suggested by the applicant.



because the applicant failed to suggest a figure.



because this figure better characterizes the invention.



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>7</sup> :</b> <b>C12N 15/10, 5/10, C07K 14/47, 16/18,</b> <b>A01K 67/027, A61K 38/17, G01N 33/50,</b> <b>C12Q 1/68</b>	<b>A3</b>	<b>(11) International Publication Number:</b> <b>WO 00/43508</b> <b>(43) International Publication Date:</b> 27 July 2000 (27.07.00)
<b>(21) International Application Number:</b> PCT/US00/01565 <b>(22) International Filing Date:</b> 21 January 2000 (21.01.00)  <b>(30) Priority Data:</b> 60/183,027                      22 January 1999 (22.01.99)                      US  <b>(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application</b> US    09/236,205 (CIP) Filed on    22 January 1999 (22.01.99)  <b>(71) Applicant (for all designated States except US):</b> INCYTE PHARMACEUTICALS, INC. [US/US]; 3174 Porter Drive, Palo Alto, CA 94304 (US).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> HILLMAN, Jennifer, L. [US/US]; 230 Monroe Drive #12, Mountain View, CA 94040 (US). YUE, Henry [US/US]; 826 Lois Avenue, Sunnyvale, CA 94087 (US). TANG, Y., Tom [CN/US]; 4230 Ranwick Court, San Jose, CA 95118 (US). AZIMZAI, Yalda [US/US]; 2045 Rock Springs Drive, Hayward, CA 94545 (US).		<b>(74) Agent:</b> HAMLET-COX, Diana; Incyte Pharmaceuticals, Inc., 3174 Porter Drive, Palo Alto, CA 94304 (US).  <b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>  <b>(88) Date of publication of the international search report:</b> 16 November 2000 (16.11.00)
<b>(54) Title:</b> CANCER-ASSOCIATED PROTEINS  <b>(57) Abstract</b>  The invention provides human cancer-associated proteins (CAP) and polynucleotides which identify and encode CAP. The invention also provides expression vectors, host cells, antibodies, agonists, and antagonists. The invention also provides methods for diagnosing, treating, or preventing disorders associated with expression of CAP.		



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
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CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 00/01565

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N15/10 C12N5/10 C07K14/47 C07K16/18 A01K67/027  
A61K38/17 G01N33/50 C12Q1/68

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12N C07K A01K A61K G01N C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	DATABASE EMBL [Online] EMBL ID HSZZ67198, Accession No. AA362051, 18 April 1997 (1997-04-18) ADAMS M.D. ET AL.: "EST71450 from H. sapiens, MCF7 cell line" XP002138148 encodes aa 221-275 of CAP2.	1-3, 8-17,20, 23
X	DATABASE GENBANK [Online] Accession No. AAB60391, GI 487348, 15 December 1995 (1995-12-15) CHISSOE S.L. ET AL.: "BCR gene" XP002138149 cited in the application the whole document	1-3, 8-17,20, 23

☒ Further documents are listed in the continuation of box C

☒ Patent family members are listed in annex

### \* Special categories of cited documents

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

- \*X\* document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

19 May 2000

Date of mailing of the international search report

21.08.00

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentaan 2  
NL - 2280 HV Rijswijk  
Tel (+31-70) 340-2040, Tx 31 651 eppo nl  
Fax (+31-70) 340-3016

Authorized officer

Galli, I

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 00/01565

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
A	WO 93 06858 A (DANA FARBER CANCER INST INC) 15 April 1993 (1993-04-15) abstract -----	1-17,20, 23

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 00/01565

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons

1. ☒ Claims Nos. because they relate to subject matter not required to be searched by this Authority, namely  
Claims 16,19,22 are directed to a method of treatment of the human/animal body. If at all possible, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☒ Claims Nos. 18,19,21,22 because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically  
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos. because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims, it is covered by claims Nos.  
1-23 partly

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: (1-23) - partly

An isolated CAP-2 polypeptide characterized by Seq. ID 2 or fragments thereof. Corresponding nucleic acids (Seq. ID 5).

Vectors, recombinant host cells, transgenic organisms, production methods, detection methods, antibodies, pharmaceutical compositions and therapeutic applications, antagonists and agonists and methods to identify them.

2. Claims: (1-23) - partly

Idem as subject-matter 1 but limited to CAP-3 (Seq. IDs 3 and 6).

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 18,19,21,22

Claims 18,19,21,22 refer to agonists and antagonists of the CAP proteins described, but do not give a true technical characterization. Moreover, no such compounds are described in the application. In consequence, the scope of said claims is ambiguous and vague, and their subject-matter is not sufficiently disclosed and supported (Art. 5 and 6 PCT). No search can be carried out for such purely speculative claims, whose word is, in fact, a mere recitation of the results to be achieved.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

## INTERNATIONAL SEARCH REPORT

In.      ation on patent family members

Internal Application No.

PCT/US 00/01565

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9306858 A	15-04-1993	CA 2120363 A	15-04-1993